UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,815	02/19/2004	Xiang Yang Zheng	LIFE-043DIV	7071

24353 7590 10/19/2005

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,815	ZHENG ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-60 and 62-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *63,64 and 67* is/are allowed.

6)☒ Claim(s) *55,56,58,59,65 and 70-72* is/are rejected.

7)☒ Claim(s) *57,60,62,[redacted],66,68 and 69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/15/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 55-56, 58-59, 65 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Coller (US Patent no. 5,854,005) or Vogler et al (US Patent no. 5,246,666, both cited in the Information Disclosure Statement filed on February 19, 2004) in

view of Sanz (US Patent no. 3,692,487, also submitted in the Information Disclosure Statement filed on February 19, 2004).

Coller teaches of a composition for use in an agglutination/coagulation assay, wherein whole blood containing platelets with glycoprotein IIb/IIIa receptors is combined with polymeric beads coated with a glycoprotein IIb/IIIa ligand. When the platelets with unblocked receptors bind to the ligands on the beads, the beads coagulate. The composition comprises polymeric beads having charged functional groups thereon, such as carboxylated polystyrene beads. The beads may be combined with an optical contrast enhancer such as a dye so that they are colored to render the results of the agglutination reaction more visible and easier to interpret. In a coagulation test, a whole blood sample containing plasma therein is combined with the carboxylated polystyrene beads and a buffer containing calcium chloride. The coagulation of the beads in the blood is monitored as an indication of the degree that the glycoprotein IIb/IIIA receptors on the platelets are not blocked. If they are blocked, then no coagulation or agglutination of the beads occurs because there is no binding between the receptors on the platelets and the ligands on the beads. Coller also teaches of a kit containing separate containers therein, one being a vial to collect a blood sample, one holding a buffer containing calcium chloride, and one containing the polymeric beads coated with GP IIb/IIIa receptor ligands. To use the kit, one simply collects a blood sample and combines the blood sample with the beads and calcium chloride buffer in a single container. See lines 1-44 in column 11 of Coller et al. Therefore, Coller teaches of a method comprising mixing together particles (i.e. polymeric beads) capable of aggregating in plasma, calcium ions (i.e. from calcium chloride) and plasma (i.e. found in whole blood).

Vogler et al teach of an additive for a blood collection container which comprises particles having a first surface region which activates clotting of blood, and a second surface region which adheres to blood clotting materials so that when a blood sample in the container clots and is centrifuged, the additive adheres to the clot and is removed from the serum layer. The particles can comprise surface modified polystyrene beads. In a coagulation time test, a sample of platelet poor plasma is added to a blood collection tube containing the polystyrene beads, the sample is incubated for 15 minutes, and then calcium chloride is added to initiate clotting. The time of coagulation is monitored and noted for the test, and the coagulation time is compared to reference samples. See Example II in column 5 of Vogler et al. Therefore, Vogler et al teach of a method comprising mixing particles capable of aggregating in plasma (i.e. surface modified polystyrene beads), calcium ions (from calcium chloride) and plasma (from platelet poor plasma).

Both Coller and Vogler et al fail to teach of performing the method comprising the mixing of a blood sample with plasma aggregatable particles and calcium ions in a container having separate compartments for separating the polymeric particles from the calcium ions until an assay is performed.

Sanz teaches of a container for performing coagulation tests on samples of plasma. The container comprises a first enclosure or compartment E1 containing a suspension of at least one blood coagulation factor that serves to initiate blood clotting, and a second enclosure or compartment E2 containing a solution of a calcium salt. The two compartments are connected to one another through a frangible membrane. When performing a blood coagulation test, a plasma sample is placed into the first compartment of the container to mix with the blood coagulation

factor, and then the frangible membrane is ruptured so as to combine the plasma and blood coagulation factor with the solution of calcium in the second compartment to initiate the coagulation process. See Figure 1, lines 43-75 in column 4 and lines 1-26 in column 5 of Sanz.

Based upon the combination of either Coller or Vogler et al with Sanz, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to perform the method taught by both Coller and Vogler et al involving the mixing of a blood sample with plasma aggregatable particles and calcium ions in the container taught by Sanz having separate compartments for holding a coagulation factor and a solution of calcium since Sanz teaches that such a container avoids complex manipulations and liquid metering operations involving potentially hazardous blood samples that require substantial equipment and highly skilled personnel. See lines 25-31 in column 2 of Sanz. By using the container taught by Sanz for performing the mixing operation of a blood sample with plasma aggregatable particles and calcium ions taught by Coller and Vogler et al, one of ordinary skill in the art would not have to manually dispense the collected blood sample, the calcium ions and the polymeric beads from one tube to another, thus simplifying the method and obtaining the advantages taught by Sanz. It also would have been obvious to one of ordinary skill in the art to provide the container taught by Sanz and used for performing the methods taught by Coller and Vogler et al with a frangible cover so as to be able to collect a blood sample via a needle directly from the circulation of an individual into the container used to perform the coagulation assay.

5. Claims 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Coller or Vogler et al in view of Sanz as applied to claims 55-56, 58-59, 65 and 72 above, and further in view of Lewis et al (submitted in the IDS dated February 19, 2004). For a teaching of

Coller, Vogler et al and Sanz, see previous paragraphs in this Office action. Coller and Vogler et al fail to teach of an aggregation enhancer in the composition comprising polymeric beads and calcium ions.

Lewis et al teach that hemoglobin is an agglutination enhancer for synthetic particles such as latex. Therefore, based upon the combination of either Coller or Vogler et al, Sanz and Lewis et al, it would have been obvious to one of ordinary skill in the art to provide the composition taught by either Coller or Vogler et al with an agglutination enhancer such as hemoglobin, as taught by Lewis et al, since the assay taught by Coller and Vogler et al involves the agglutination of synthetic particles (i.e. polymeric beads).

6. Claims 57, 60, 62, [redacted], 66 and 68-69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a container having three compartments therein separated by frangible barriers, with one compartment holding plasma aggregatable particles, one compartment holding a solution of calcium and one compartment holding a citrated plasma sample. In addition, none of the prior art of record teaches or fairly suggests a coagulation test evaluation system comprising at least one frangible bead containing plasma aggregatable particles, at least one frangible bead containing a solution of calcium ions and a container for holding the frangible beads.

7. Claims 63-64, 67 are allowable as is over the prior art of record for the same reasons as given above.

8. Applicant's arguments filed August 16, 2005 have been fully considered but they are not persuasive.

The previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on June 17, 2005 have been withdrawn in view of Applicants' amendments to the claims.

Applicants argue the rejections of the claims under 35 USC 103 using the combination of references to Coller, Vogler et al, Sanz and Lewis et al by stating that none the references teach of a control composition, and therefore, none of the references teach or suggest a container for a control composition as now recited in independent claim 55. In response to this argument, it is noted that the amended description of the container in instant claim 55 as a "control composition container" does not further patentably distinguish the container from those taught by Coller, Vogler et al and Sanz since a container is defined by its structure and the solution or composition it holds, not by the intended use of the composition it holds. The recitation of a "control composition container" is merely an intended use of the composition recited in the instant claims that comprises plasma aggregatable particles and a solution of calcium ions. Since the composition taught by both Coller and Vogler et al comprises plasma aggregatable particles and a solution of calcium ions held by some type of container, similar to the instant invention, the composition taught by these references can inherently be used as a "control composition", and the container in which the compositions are held can inherently be termed "a control composition container". In addition, the composition taught by Sanz held by a container having two separate compartments therein can also be considered a "control composition" since the composition contains therein defined amounts of a blood coagulation factor and a solution of calcium ions.

For the above reasons, Applicants' arguments are not found persuasive.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

October 17, 2005

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700